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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 00N–1269]

RIN 0910–AA94

Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to June 22, 2001, the comment period for the proposed rule that appeared in the **Federal Register** of December 22, 2000 (65 FR 81082). The proposed rule would, among other things, require that the labeling of new and recently approved prescription drug and biological products include a section containing highlights of prescribing information and a section containing an index to prescribing information. The agency is extending the comment period in response to a request by a group representing pharmaceutical manufacturers. The agency is taking this action to provide interested persons additional time to submit comments on the proposed rule.

DATES: Submit written or electronic comments by June 22, 2001.

ADDRESSES: Submit written comments to the Docket Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the Internet at http://www.fda.gov/dockets/ecomments.

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FOR FURTHER INFORMATION CONTACT: Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD-42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, Ostrove@CDER.FDA.GOV

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 22, 2000 (65 FR 81082), FDA published proposed regulations that would revise the format of prescription drug and biologic labeling to make it more accessible, readable, and user-friendly for health care professionals. Comments on the proposed rule were to be submitted by March 22, 2001. The proposed format provisions would require that drug product labeling (also known as the "package insert," "direction circular," or "package circular ") be presented in three sections: (1) A section containing highlights of prescribing information, (2) an index section, and (3) a section containing comprehensive prescribing information. The highlights of the prescribing information section would appear first in labeling and would include information that practitioners most commonly refer to and view as most important. Specific headings within this section would also reference the location of more detailed information on a topic. The index section would contain a list of the major and minor subheadings in the comprehensive prescribing information section to assist practitioners in finding specific information of interest to them. The comprehensive prescribing information section would include the detailed information that constitutes current labeling. The proposed rule would reorder and reorganize this information to increase the prominence of important information and make it easier to find. The proposed format changes are based on research FDA conducted with physicians and on comments received from the public in response to a **Federal Register** document issued, and public meeting held, before the proposed rule.

In addition to revising the format of labeling, the proposed rule would make minor changes to its content and establish minimum graphical requirements, including a minimum type size. The proposal would also amend prescription drug labeling requirements for older drugs to require that

certain types of statements currently appearing in labeling be removed if they are not sufficiently supported. Finally, the proposal would eliminate certain unnecessary statements that are currently required to appear on prescription drug product labels (i.e., on the immediate container of a drug product) and move other information that is currently required to appear on labels to the labeling (i.e., the package insert).

FDA received a request from the Pharmaceutical Research and Manufacturers of America to extend the comment period an additional 90 days. The request stated that the proposed rule raises significant legal, compliance, and implementation issues for the pharmaceutical industry, and that additional time is necessary to formulate a response. In response to this request, and to provide all interested persons additional time to comment on the proposed format changes and other aspects of the proposed rule, FDA is extending the comment period to June 22, 2001.

II. Comments

Interested persons may by June 22, 2001, submit written or electronic comments regarding the proposed rule. Written comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Electronic comments may also be submitted electronically on the Internet at http:// www.fda.gov/dockets/ecomments. Once on this Internet site, select "OON–1269 Labeling for Human Prescription Drug/Biologic Products" and follow the directions.

Dated: March 23, 2001
March 23, 2001

Ann M. Witt
Acting Associate Commissioner for Policy

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